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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/31/2003

Luciano Trinchese

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09/15/2006

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,918

Applicant(s)

TRINCHESE, LUCIANO

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23,25,27-42 and 47-66 is/are rejected.
- 7) ☒ Claim(s) 24,26 and 43-46 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03/01/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/29/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 18-23, 27-42 and 47-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Elstrom et al. (US Pat. 5,540,691).

Elstrom et al. disclose an apparatus for the osteosynthesis of bone fractures by means of locked endomedullary nailing, of the type comprising: a tubular nail (Fig. 5, ref. 30) defining an internal coaxial through channel (Fig. 1, ref. 25), provided with transverse through holes (Fig. 1, ref. 26 and 28) whose axis intersects the axis of the nail (Fig. 1) and able to be inserted in a medullar channel of a bone (Fig. 1); a device

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(column 3, lines 56-62) for locating the axis of a predetermined hole selected among said holes, along which the bone is to be drilled to drive a corresponding screw for locking the nail on the bone; wherein the locating device comprises: a source of electromagnetic power (column 3, lines 60-62); an emitter of the electromagnetic power in the form of non-ionizing electromagnetic radiation (column 3, lines 60-62), able to be inserted inside the nail along the internal channel from a proximal end of the nail at least to a working position (column 3, lines 56-61), located on the axis of the predetermined hole, in which at least part of the non-ionizing electromagnetic radiation is directed from the emitter, through the predetermined hole, on an inner superficial portion of the cortex of the bone corresponding to the axis of the predetermined hole and generates, beyond an outer superficial portion of the cortex of the bone, also corresponding to the axis of the predetermined hole, a signal detectable from the exterior having an intensity distribution with its centroid in correspondence with the axis of the predetermined hole (column 3, lines 62-67, and column 4, lines 1-5); a line for transmitting the electromagnetic power from the source to the emitter (column 4, lines 29-33). The centroid of the intensity distribution of the signal detectable from the exterior coincides with an intensity peak (column 8, lines 62-66). The non-ionizing electromagnetic radiation egressing from the emitter has its spectrum distributed on a predetermined interval of wavelengths selected in the range that goes from near ultraviolet to mid infrared (column 4, lines 17-18), ends included, the signal being essentially determined by the radiation portion transmitted through the bone tissues. The electromagnetic radiation egressing from the emitter is visible light (column 4, lines 17-18). The

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wavelengths belonging to the predetermined interval are comprised between 600 nanometres and 700 nanometres (column 4, lines 18-20). The wavelengths belonging to the predetermined interval are comprised in the infrared range (column 4, lines 17-18). The emitter comprises an optical collimation system that collimates the electromagnetic radiation in a beam within a predetermined solid angle centered on the optical system, the solid angle being coaxial with the predetermined hole when the emitter is in the working position (column 4, lines 33-42). The source directly generates the non-ionising electromagnetic radiation (column 3, lines 60-62), the transmission line comprising a waveguide (Fig. 1, ref 34)(column 4, lines 28-29) for carrying the electromagnetic radiation to the emitter. The source directly generates the non-ionising electromagnetic radiation, wherein the transmission line comprises a waveguide (Fig. 1, ref 34)(column 4, lines 28-29) for carrying the electromagnetic radiation to the emitter and wherein the optical system, coupled to the waveguide, comprises a collimating lens and (in the laser, column 5, lines 47-50) a deflector (Fig. 4, ref. 32) that deflects the radiation coming from the waveguide in the solid angle. The source comprises an electrical power generator (column 4, lines 30-33), the emitter comprises a heating element and the transmission line comprises an electrical wire connecting the heating element to the electrical power generator, the heating element emitting, when excited by the electrical power, electromagnetic radiation at wavelengths in the thermal infrared region. The light that is emitting the infrared light (column 4, lines 17-18) would become warm; hence it can be considered a heater and an emitter of infrared light. The light is attached to the power supply with electrical wiring (column 4, lines 30-33).

The source comprises a surgical power laser (column 5, lines 47-50) and the emitter comprises a focusing optical system (column 5, line 47-50) coupled with the transmission line, which, when the emitter is in the working position, directs and focuses the laser beam on a part of bone tissue in correspondence with the axis of the predetermined hole, the signal being defined by the perforation of the bone tissue operated with the laser beam, the apparatus further comprising protecting screens (column 7, lines 59-62), able to be positioned in removable fashion around the fractured part to protect the operator from the action of the laser beam. A centroid of the intensity distribution of the signal detectable from the exterior coincides with an intensity peak (column 3, lines 62-67, and column 4, lines 1-5) and in that the apparatus further comprises a contrast enhancement device (column 8, lines 9-13) which can be positioned on the axis of the predetermined hole externally to the bone and acts on the portion of radiation transmitted through the bone tissues enhancing the contrast between the intensity peak and a peripheral part of the signal and improving the resolution in the identification of the position of the axis of the predetermined hole. The contrast enhancement device comprises an attenuating filter for attenuating the intensity of the radiation (column 5, lines 39-43). The transmission spectrum of the attenuating element has a maximum for wavelengths between 600 nm and 700 nm (column 5, line 37). The attenuating filter has an adjustable attenuation factor (column 5, lines 22-25). The emitter egresses electromagnetic radiation with a predetermined polarization state (since it is coming from a laser) and wherein the attenuating filter comprises a polarizer element to attenuate the portion of radiation transmitted by the bone tissues not having

the polarization state of the radiation originally egressing from the emitter (column 5, lines 35-39 and column 8, lines 23-30). The apparatus further comprises a detector of the signal and a related image converter, able to be positioned externally to the bone for identifying the centroid of the intensity distribution of the signal and visualizing its position (column 8, lines 9-13). The apparatus further comprises an arrest reference (Fig. 5, ref. 70) for arresting the insertion of the emitter in the internal channel when the emitter reaches a working position. The arrest reference comprises an abutment element (the distal end of ref. 30, Fig. 3), able to abut the proximal end of the nail or an extension thereof and able to be positioned along the transmission line in a position of arrest of the insertion of the transmission line in the internal channel corresponding to the working position of the emitter. The arrest reference comprises elements for stopping the motion of the transmission line in the nail when the emitter reaches the working position, acting between the transmission line and the wall of the internal channel and able to be elastically disengaged. The elements can be considered to be the transmission line (Fig. 3, ref. 30) and the wall of the internal channel (Fig. 1 ref. 24).

The terminal segment of the transmission line destined to be inserted in the internal channel is enclosed by a substantially rigid sheath (column 7, lines 24-26) and wherein the abutment element and the proximal end of the nail or its extension comprise mutual engagement means for the certain orientation of the emitter with an axis of emission thereof parallel to the axis of the predetermined hole (the distal end of ref. 30, Fig. 3 in conjunction with the spacing of the lights ref. 56 and 58, Fig. 3).

At least the terminal segment of the transmission line destined to be inserted in the internal channel comprises a support element with high torsion constant. At least the terminal segment of the transmission line destined to be inserted in the internal channel is enclosed by a substantially rigid sheath (column 7, lines 24-26). The apparatus further comprises a fastening pin (Fig. 5, ref. 64) for fastening a tubular hand piece to the nail, the fastening pin being tubular, coaxial to the nail and with its inner diameter corresponding to the diameter of the internal channel of the nail.

The apparatus further comprises means for the certain orientation of the emitter with an axis of emission thereof parallel to the axis of the predetermined hole at least in proximity thereto. The means for the certain orientation of the emitter comprise means of mutual interference between the terminal segment of the transmission line, destined to be inserted in the internal channel, and the wall of the internal channel, which determine the orientation of the emitter allowing the transmission line to slide in the internal channel. The means can be considered to be the wall of the internal channel (Fig. 1 ref. 24) and the terminal segment of the transmission line (Fig. 3, near ref. 60).

The apparatus further comprises automatic positioning means for automatically positioning the emitter at the height of the plane defined by the axis of the predetermined hole and by the axis of the nail, acting at least when the emitter, inserted in the internal channel, is in proximity to the working position. The automatic positioning means comprise means for centering the emitter on the axis of the nail acting at least when the emitter, inserted in the internal channel, is in proximity to the working position. The means for centering the emitter of the axis of the nail comprise at least a widening

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of the diameter of a sheath of the transmission line at least in proximity to the emitter (Fig. 6, the widening near ref. 31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 21, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elstrom et al. (US Pat. 5,540,691) in view of Alexander et al. (US Pat. 6,309,392).

Elstrom et al. disclose the claimed invention except for the means for centering the emitter on the axis of the nail comprising, at least in proximity to the predetermined hole, a narrowing of the internal channel around the axis of the nail.

Alexander et al. disclose means for centering the emitter on the axis of the nail comprising, at least in proximity to the predetermined hole, a narrowing of the internal channel around the axis of the nail (Fig. 1, ref. 22), used to guide a power transmission cable and tools to the transverse bore (column 2, lines 45-49).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the nail of Elstrom et al. with the narrowing of the internal channel around the axis of the nail of Alexander et al., in order to guide

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the power transmission cable and emitter of Elstrom et al. towards the transverse bores (column 2, lines 45-49).

Claims 1, 3, 13-17 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elstrom et al. (US Pat. 5,540,691).

With regard to claim 15, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the attenuating element with "neutral density" in the visible range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claims 16, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the attenuating element to attenuate the transmission of the radiation whose wavelength is less than 600 nm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

With regard to claim 64, Elstrom et al. disclose the claimed invention except for the nail comprising emitters, already appropriately positioned and aligned at least in front of the corresponding distal holes, and corresponding segments of transmission line, also integrated in the nail and provided, at an opposite end relative to the emitters, with connectors to corresponding extensions of the transmission line through to the source. It would have been obvious to one having ordinary skill in the art at the time the

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invention was made to have constructed the nail comprising emitters, already appropriately positioned and aligned at least in from of corresponding distal holes, and corresponding segments of transmission line, also integrated in the nail and provided, at an opposite end relative to the emitters, with connectors to corresponding extensions of the transmission line through to the source, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. Howard v. Detroit Stove Works, 150 U.S. 164 (1893).

Allowable Subject Matter

Claims 24, 26, 43, 44, 45, 46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER